OAH 11-0900-30534

STATE OF MINNESOTA
OFFICE OF ADMINISTRATIVE HEARINGS

FOR THE COMMISSIONER OF HEALTH

In the Matter of Robbinsdale
Rehabilitation and Care Center;
Survey Exit Date: January 10, 2013

RECOMMENDED DECISION

This matter was the subject of an independent informal dispute resolution (IIDR) conducted by Administrative Law Judge Barbara L. Neilson on May 17, 2013. The OAH record closed at the conclusion of the conference that day.

Christine Campbell, Division of Compliance Monitoring, appeared on behalf of the Minnesota Department of Health (MDH or Department). Mary Cahill, Planner Principal with the Division of Compliance Monitoring, and Sandra Nelson, RN Surveyor, also participated in the conference on behalf of the Department.

Dawn Wozniak, Regional Director of Clinical Operations for Extended Care, appeared on behalf of Robbinsdale Rehabilitation and Care Center (Facility). Kathleen Pankratz, Administrator; Mindy Kapaun, Certified Occupational Therapy Assistant; Amanda Lymangood, Manager of the Rehabilitation Department; Kayla Salazar, Director of Nursing; and Kelly Murphy, Nurse Manager for the Transitional Care Unit, also participated in the conference on behalf of the Facility.

Based on the exhibits submitted and the arguments made and for the reasons set out in the Memorandum below, the Administrative Law Judge makes the following:

RECOMMENDED DECISION

As discussed more fully below, the Administrative Law Judge concludes that Tag F 309 is supported in substance by the facts and should be affirmed, subject to deletion of certain findings that were not supported by the record and reduction in the scope and severity level from level G to level D. Tag F 329 is supported in substance by the facts and should be affirmed at the recommended scope and severity level of D, subject to deletion/revision of certain findings that were not supported by the record.

Dated: June 10, 2013

s/Barbara L. Neilson
BARBARA L. NEILSON
Administrative Law Judge

Reported: Digitally recorded (no transcript prepared).

NOTICE

In accordance with Minn. Stat. § 144A.10, subd. 16(d)(6), this recommended decision is not binding on the Commissioner of Health. As set forth in Department of Health Information Bulletin 04-07, the Commissioner must mail a final decision to the Facility indicating whether or not the Commissioner accepts or rejects the recommended decision of the Administrative Law Judge within 10 calendar days of receipt of this recommended decision.

MEMORANDUM

Introduction

On January 10, 2013, a survey team for the Minnesota Department of Health concluded a recertification survey at the Robbinsdale Rehabilitation and Care Center (the Facility). Following the completion of the survey on January 10, 2013, the survey team issued a Summary Statement of Deficiencies to the Facility.[1] In this proceeding, the Facility challenges the deficiencies identified by Tags F 309 and F 329. Both deficiencies relate to the same Resident, who is identified as Resident 48.

Tag F 309 alleges a violation of the quality of care standards set forth in 42 C.F.R. § 483.25. The Department contends that the Facility failed to conduct a reassessment and provide adequate pain management for Resident 48 when the Resident complained of acute and persistent shoulder pain.[2] Before deciding that this violation occurred, the survey team reviewed records and interviewed Resident 48 and certain Facility staff, including the Certified Occupational Therapist Assistant, a Registered Nurse, the Facility Medical Director, and the Interim Director of Nursing.[3] The F 309 violation was cited at a scope and severity level of G, based upon the team's conclusion that the deficiency was isolated in scope and resulted in actual harm that was not immediate jeopardy.

Tag F 329 alleges a violation of the requirement in 42 C.F.R. § 483.25(l) that a resident's drug regimen be free from unnecessary drugs. The Department alleges that the Facility failed to ensure that Resident 48 was free of unnecessary medications related to the use of Ambien.[4] The Department contends that the Resident received a high dose of Ambien for an extended period of time based on his physician's orders that it be given PRN (as needed), with no plan for discontinuance. The Department argues that the Facility failed in its responsibility to monitor and identify unnecessary medications and did not address the issue in its assessment or interventions or discuss it with the Resident's physician. Before deciding that this violation occurred, the survey team reviewed records and interviewed Resident 48 and certain Facility staff, including a Registered Nurse, a consultant pharmacist and the Interim Director of Nursing.[5] This

[1] Exhibit (Ex.) 5.
[2] *Id*. at 5-5 – 5-16.
[3] *Id*. at 5-4 – 5-16.
[4] *Id*. at 5-16.
[5] *Id*. at 5-17 – 5-19.

deficiency was cited at a scope and severity level of D, based upon the team's determination that it was an isolated deficiency that resulted in minimal discomfort to the resident and/or had the potential (not yet realized) to compromise the resident's ability to reach his highest practicable physical, mental or psychosocial well-being.

In this IIDR proceeding, the Facility asserts that both of the alleged violations should be rescinded because there were no deficient practices by the Facility.

Factual Background

Resident 48 is a 62-year-old man who was admitted to the Facility on December 11, 2012, for rehabilitation following knee replacement surgery. At the conclusion of his stay in the Facility, the Resident planned to return home with a personal health assistant. The Resident was discharged from the Facility on January 22, 2013.[6]

The Resident's diagnoses at the time he was admitted to the Facility included Type II diabetes, hypertension, mild intermittent asthma, bilateral shoulder pain and arthritis, osteoarthritis, and depression. He was alert and oriented and was able to effectively communicate his needs and direct his own cares. He had managed his pain medications on his own at home prior to his hospitalization.[7] The Resident's hospital records dated December 10, 2012, indicated that he indicated that he has a history of prior drug abuse (cocaine), "[d]ifficult pain control," and "resistance to therapies." His hospital records also noted that he had had a steroid injection in his shoulder on December 8, 2012, due to degenerative joint disease.[8]

Resident 48 had been prescribed Ambien PRN (as needed) for sleep prior to his hospitalization. The dose was one 10 mg. tablet at bedtime. He had also been prescribed two pain medications prior to his admission which he continued to take during his stay at the Facility: (1) a long-acting narcotic pain medication that he received twice a day (Oxycontin, 10 mg, 1 tablet every 12 hours); and (2) a short-acting hydrocodone-acetaminophen pain medication that he could take as needed every 4 hours (Norco, 7.5-325 mg, 1-2 tablets every 4 hours).[9]

The Facility prepared a "Plan of Care: Pain Management" for the Resident on December 11, 2012. Among other things, the Plan noted that the Resident had acute and persistent pain and alteration in comfort related to pain secondary to bilateral shoulder pain, osteoarthritis, and the knee replacement surgery. The goals noted on the Plan of Care included decreasing the Resident's persistent pain to a tolerated level so he could function in daily life; ensuring that the Resident's pain was relieved within

[6] Comments of Dawn Wozniak; Ex. 5 at 5-17; Ex. 9 at 9-1, 9-2.
[7] Ex. 9 at 9-1, 9-2, 9-4; Comments of D. Wozniak. The Statement of Deficiencies and Plan of Correction stated that the Resident scored 27/30 on a SLUMS cognitive testing tool on December 17, 2012, which indicated normal cognitive status. In addition, the Minimum data Set dated December 20, 21012, noted that the Resident's scored a 14 on the Brief Interview of Mental Status, which signified that he had intact cognition. Ex. 5 at 5-7.
[8] Ex. AL.
[9] Ex. 8 at 8-8, 8-10, 8-13, and 8-14; Ex. AQ.

30 to 60 minutes after he was given pain medication or treatment; and enabling the Resident to participate in activities of daily living (ADLs), engage comfortably in therapies, and attend recreational activities. Interventions set forth in the Plan of Care included administering pain medication as ordered; monitoring and recording the effectiveness of PRN medication; observing the Resident during rest and during movement for pain; assessing verbal and non-verbal signs and symptoms of distress of pain unrelieved by ordered treatments and medications; providing cold packs; and encouraging mobility and physical activity as tolerated.[10]

The Facility also completed a Pain Data Collection and Assessment form regarding Resident 48 on December 11, 2012. The information on the form was obtained from the Resident and from his medical records. The Resident answered "yes" when asked whether pain had made it hard for him to sleep at night over the past five days, and stated that was "very important" to him to "completely eliminate" his pain. The Resident was asked to rate his pain on a scale of 0-10, with 10 defined as the "most intense pain imaginable." He rated his pain at that time as 10/10, and indicated that his pain level was typically 7/10 three hours after medication was given. The Resident stated that his pain medication was effective to some extent and that ice packs could help make him more comfortable, but noted that the pain associated with his diabetes and arthritis was always present.[11] The form did not include any notation regarding the steroid injection in his shoulder that the Resident had received on December 8, 2012, for degenerative joint disease.[12]

Physical and occupational therapy evaluations were also conducted regarding the Resident shortly after his admission to the Facility, and PT and OT Plans of Care were prepared for him. The portion of the PT Plan of Care describing the Resident's medical history noted that he had bilateral shoulder pain and shoulder arthritis. The Plan also indicated that the Resident rated his current pain level as 10/10; complained of "constant" pain in knee, hip, and back; presented with "limited" active range of motion (AROM) and strength in his shoulders; and noted that his shoulder AROM was approximately 90 bilateral "with pain."[13] According to a note entered on December 12, 2012, the Resident rated his pain as 9/10 and 10/10 after exercise with no signs or symptoms of facial grimace or pain. Due to time his pain medication was given, Facility staff decided that the Resident's PT each day would be scheduled at 10:00 a.m.[14] The Resident's OT Plan of Care noted that occupational therapy was necessary for the Resident to increase his independence with activities of daily living (ADL). The OT Plan noted that the Resident rated the pain in his right knee and bilateral shoulders as 10/10 and the pain in his bilateral shoulders alone as a 9/10. The goals set forth in the OT Plan related to toileting, upright standing, and decreasing the Resident's reported pain for his bilateral shoulders to 7/10.[15]

[10] Ex. 9 at 9-10.
[11] Ex. 8 at 8-1 - 8-2.
[12] Ex. 9 at 9-1; *see also* Ex. V.
[13] Ex. W.
[14] Ex. Y.
[15] Ex. AA.

On December 17, 2012, a registered nurse employed by the Facility conducted a pain interview with the Resident. At that time, the Resident said that he had frequently experienced pain or hurting over the last five days and that his worst pain intensity during the prior five days had been 9/10. However, he indicated that the pain had not made it hard for him to sleep at night during that time period and he had not limited his day-to-day activities due to pain.[16]

The Resident received physical therapy and occupational therapy at the Facility from the time of his admission until approximately January 9, 2013, when the therapy was discontinued at the Resident's request. The PT Daily Treatment Notes for December 20, 2012, indicated that, while the Resident was making gains, his "pain [was] limiting." The Physical Therapist recommended that the Resident use ice to decrease pain/edema. A note by the Physical Therapy Assistant the same day indicated that the Resident had complained that his pain was not controlled by his medications. The PTA told the Resident to discuss it with his doctor at his appointment the following Monday. According to her note, she also notified nursing of "pain limiting therapy and not controlled by pain meds."[17] However, there is no mention of this in the Nursing Progress Notes that were included in the IIDR record and no evidence that the Facility's nursing staff assessed the Resident's pain after receiving notice from physical therapy staff.[18]

The Resident's physical therapy notes for the next day, December 21, 2012, indicated that the Resident tolerated therapeutic exercises well although he had several complaints of knee pain.[19] The occupational therapy notes indicated that the Resident reported that his shoulder pain was 10/10 prior to treatment with E-Stim (electrical stimulation) and IFC (interferential current) motor sensory therapy, and 8/10 after treatment was concluded.[20]

On December 27, 2012, Facility nursing staff notified Dr. Kearns (the Resident's orthopedic physician) that the Resident was continuing to complain of severe pain in his knee and had run out of Norco that morning. Dr. Kearns saw the Resident that day and indicated in his progress notes that the Resident was making satisfactory progress with the right knee replacement. He advised the Resident to continue with physical therapy and weight-bearing activities as tolerated and return to his office in four weeks. He also re-prescribed Norco.[21] There is no indication in the records that the Resident discussed his shoulder pain during that appointment.

On December 31, 2012, the OT Daily Treatment Note indicated that the Resident stood five minutes while attending to bilateral upper extremity activity but was "unable to tolerate further standing due to increased pain." The notes stated that the Resident performed a large pegboard activity with bilateral upper extremities to increase his grip

[16] Ex. N; Comments of D. Wozniak.
[17] Ex. 8 at 8-4.
[18] *See* Ex. AO.
[19] Ex. 8 at 8-4.
[20] Ex. AC.
[21] Exs. K and L.

strength and range of motion. He also ambulated to and from the bathroom and completed a toileting task, and indicated that he had "increased ease" with standing and ambulation. In addition, E-Stim therapy was completed to both of the Resident's shoulders "to reduce level of pain." On that date, the Resident reported his pain was 10/10 prior to treatment and 8/10 after completion of treatment.[22] On December 31, 2012, and January 1, 2013, the Resident reported that his pain was 10/10 prior to therapy and lower (6/10 and 4-5/10) after therapy.[23]

Although the Resident had informed Facility therapists of the shoulder pain he was experiencing, he did not mention it to the nurses who were caring for him in the Facility until January 1, 2013.[24] On January 1, 2013, the Occupational Therapist noted that the Resident "is frustrated with pain in bilateral shoulders, consulted nursing staff regarding pain in bilateral shoulders." The Resident rated his pain that day as 10/10 prior to treatment of his left shoulder and as 8/10 following treatment.[25]

On January 2, 2013, a registered nurse interviewed the Resident and, on January 3, 2013, completed a Pain Data Collection and Assessment form. The form noted that the reason for the assessment was the onset of new pain, and stated that the Resident "recently started complaining of bilateral shoulder pain." In contrast to his responses during his prior pain interview on December 17, 2012, the Resident stated that pain had made it hard for him to sleep at night over the past five days, and he had limited his day-to-day activities due to pain during that time period. He said that activities exacerbated his shoulder pain, but the pain was relieved by Norco, ice packs, and warm packs. The Resident rated his pain at the time of the interview as 6/10, and his pain when moving around, getting up to go to the bathroom, or performing activities as 10/10. He indicated that his pain one hour after medication was 5/10, and three hours after medication was 6/10. He asserted that the lowest level of pain he had experienced over the past five days was 4/10. The nurse indicated on the form that the Resident's PT/OT may be associated with pain.[26]

On January 3, 2013, Resident 48 saw his primary physician, Dr. Robert Suurmeyer, for follow-up of his knee replacement. The Resident's main concern at that time was "the aggravation of his shoulder pain during the transfers and PT efforts for his knee." Dr. Suurmeyer diagnosed the Resident with shoulder arthritis in his right shoulder, with worsening symptoms. Dr. Suurmeyer provided the Facility with a written prescription for the hydrocodone-acetaminophen, 7.5-325 mg, that had previously been prescribed but did not make any change in the Resident's prescriptions. He indicated that the shoulder issue "will need to be addressed by the ortho consultants." Dr. Suurmeyer's office also provided the Resident with written information relating to chronic pain treatment approaches.[27] The Physician Orders and Progress Notes completed by Dr. Suurmeyer indicated that the pain in the Resident's right knee was

[22] Ex. A.
[23] Ex. 8 at 8-5.
[24] Comments of Kelly Murphy; Comments of D. Wozniak.
[25] Ex. A.
[26] Ex. AF.
[27] Ex. 9 at 9-2 – 9-9; Ex. H; Comments of K. Murphy.

less but the pain was worse in both shoulders and had been aggravated by daily PT and daily tasks of living. His updated diagnosis was osteoarthritis of shoulders with aggravation. He ordered "review [of] same meds, with consideration for ortho referral for reassessment of shoulder pain."[28]

After the Resident returned from his doctor appointment on January 3, 2013, he met with the Physical Therapy Assistant. The PTA discussed "working through pain as if at home" but the Resident was "frustrated and not receptive." The Resident declined further therapy that day. On January 4, 2013, the Physical Therapist noted that the Resident had reported that his knee pain was at 10/10 but "exhibit[ed] no s/s [signs/symptoms] of being in pain." He did not finish the exercises and accused the Physical Therapist of treating him like a "slave" and not allowing him to rest as she did other individuals.[29]

On January 7, 2013, a Sleep Assessment was completed regarding Resident 48. The Resident indicated that his sleep concern related to "knee pain" and "shoulder pain" and that the problem had begun after his surgery. When asked what keeps him awake at night, he responded, "knee pain." The Resident indicated that medications help him fall back asleep. The Assessment form mentioned that the Resident had previously had an injection to his shoulder and also included a notation that ice packs and warm packs had been offered in the past and the Resident had refused them at times. The individual performing the assessment concluded that "meds are effective per review of sleep pattern."[30] Although it was noted in the Resident's post-operative summary that testing for obstructive sleep apnea should be considered,[31] the Sleep Assessment performed by the Facility did not address this issue.

A Progress Update was completed by the OT Assistant on January 8, 2013. The Update indicated that the goal with respect to pain was that the Resident "will report decreased pain for bilateral shoulders to 7/10 . . . by e-stimulation in order to complete self care tasks." The Update noted that, on January 1, 2013, the Resident reported a pain scale rating of 5-8/10 for bilateral shoulders and that, as of January 8, 2013, the Resident reported a pain scale rating of 6-8/10 for bilateral shoulders. According to the Update form, E-Stim therapy was being provided daily to decrease the level of pain and the Resident was having reduced pain compared to the situation at the time of the OT evaluation. The notes further stated:

> Pt [patient] participated in therapy for all scheduled tx [treatment] sessions this week. Pt continues to have pain in bilateral shoulders which pt is addressing with e-stim. Pt reporting e-stim is helping to reduce level of pain in bilateral shoulders. Therapy also working to increase standing tolerance to increase activity tolerance and overall strength. Pt is progressing towards meeting goal. Pt will benefit from continued skilled

[28] Ex. G.
[29] Ex. 8 at 8-6.
[30] Ex. 8 at 8-7.
[31] *See* Ex. AL.

OT services to increase activity tolerance and strength to increase ease with ADL tasks.[32]

On January 9, 2013, a Facility nurse discussed with the Resident the importance of alerting therapy and nursing staff about any change in pain control. When the Resident stated, "Well, I didn't come here for my shoulder pain," the nurse told him that it was the Facility's responsibility to address the shoulder issue now that he had raised it.[33] The Resident's Plan of Care was also updated on January 9, 2013, to indicate that the Resident had complained of increased pain in his shoulder due to occupational therapy and to add as an additional comfort measure the application of warm packs to address the shoulder pain. The Care Plan included a notation that occupational therapy had been discontinued at the Resident's request.[34] Nursing notes for later in the evening on January 9, 2013, indicate that the Resident's shoulder pain decreased from 9/10 to 4/10 after medication was given and a warm pack was applied. According to the nurse's progress notes, the Resident told the nurse that the warm packs were helpful and the nurse encouraged him to call when he would like warm packs again.[35]

During his interview with one of the surveyors on January 10, 2013, Resident 48 reported that he stopped going to OT because it was causing more pain in his shoulders. The Resident said that the therapists "twisted" his words and reported the treatment was helping his shoulders when in fact it was making them worse. The Resident acknowledged to the surveyor that he had always had some pain in his shoulders while he was at home but alleged that his shoulder pain now was much worse. He asserted that he could not comb his own hair and had difficulty going to the bathroom because of the shoulder pain. He also reported that the shoulder pain was keeping him up at night and would start up if he rolled over in bed. He stated that he felt that the shoulder pain was decreasing his ability to recover from the knee surgery and was causing him to feel "sad and upset." When Resident 48 attempted to raise his arms during the interview, the surveyor observed facial grimacing. The Resident told the surveyor that the primary care physician he saw merely refilled his prescription and did not do anything further for the shoulder pain. He claimed that he had made his own appointment with his "shoulder doctor" for January 17, 2013, and stated that Ms. Murphy had told him he could not make his own appointments. He said that he was not sure whether he was going to get to go to the appointment or not. Finally, the Resident said he took Ambien at home as needed but not every night like he had while in the Facility.[36]

The Facility disagreed with the Resident's version of the events leading up to his orthopedic appointment. Because Dr. Suurmeyer's order merely stated that a referral to orthopedics should be "considered," the Facility asserted that it was necessary to seek clarification of Dr. Suurmeyer's intent prior to making the appointment. This is apparently consistent with the information Ms. Murphy provided to the survey team at

[32] Ex. D.
[33] Ex. U.
[34] Ex. 9 at 9-10; Comments of Sandra Nelson.
[35] Ex. U.
[36] Ex. 5 at 5-5 – 5-6.

the time of their interview. The Facility also maintained that the Resident had not, in fact, made the orthopedic appointment himself, and pointed out that it arranged transportation to ensure that the Resident kept the appointment.[37]

On January 17, 2013, the Resident saw John Kearns, M.D., at Twin Cities Orthopedics, P.A. Dr. Kearns was the surgeon who had previously performed his knee replacement. Amanda Lymangood, Manager of the Facility's Rehabilitation Department, accompanied the Resident to this appointment. According to the report issued by Dr. Kearns, the Resident was not in acute distress at the time. The Resident told Dr. Kearns that he had a long history of problems with his shoulders and had been told in the past that he has arthritis. The Resident reported that he had significant limitation in his use of his shoulders and had experienced difficulty using a walker due to his shoulder pain. Based on his examination of the Resident and review of prior x-rays, Dr. Kearns noted that there was "significant osteoarthritic change of the shoulders, essentially bone-to-bone contact." Dr. Kearns recommended intra-articular cortisone injections at Abbott Northwestern Hospital. He also changed the Resident's pain medication to Vicodin 7.5/325 one tablet every six hours as needed, reflecting a reduction in narcotic analgesia. Dr. Kearns indicated that the Resident's knee was healing well and stated that the Resident's pain and medical status reflected "typical behavior" that he had demonstrated with his previous knee surgery. Ms. Lymangood explained to Dr. Kearns what the nurses and therapists at the Facility had been doing, showed him notes, and asked if the Facility could do anything more to help with the Resident's pain. Dr. Kearns said the Facility's "efforts are great" and the Facility was "doing everything [it] should be."[38]

During a pain assessment interview held prior to his discharge on January 22, 2013, the Resident indicated that he had only "occasionally" experienced pain during the last five days and rated the intensity of his worst pain over the last five days as 8/10. He answered "no" when asked if pain had made it hard for him to sleep at night during the past five days or if it had caused him to limit his day-to-day activities.[39]

On January 25, 2013, during a post-discharge telephone call with Facility staff, the Resident indicated that he would stay with the Facility again in the future if the need arose. He said that the Facility provided "good" therapy and other care and his only complaint was that "Kelly said I'm faking pain." He stated that he was "satisfied" and was "doing great."[40] The Resident elected to return to the Facility in March 2013, and had again been discharged from the Facility by the date of the IIDR meeting.[41]

When the Department's survey team interviewed Ms. Murphy, she stated that she was not aware of the Resident's shoulder pain until January 1, 2013, and said that she had not read any of the PT or OT notes. During separate interviews, the Facility's medical director said that he was not aware of the Resident's pain status and the

[37] Comments of K. Murphy; Comments of D. Wozniak; Ex. J; Ex. 5 at 5-15 – 5-16.
[38] Ex. 9 at 9-11; Ex. J; Ex. M; Ex. AM-1; Comments of Amanda Lymangood.
[39] Ex. AK.
[40] Ex. AM; Comments of A. Lymangood.
[41] Comments of D. Wozniak.

Facility's interim director of nursing indicated that the Facility does not have a policy pertaining to updating the physician regarding a resident's frequent PRN medication use.

Discussion

Applicability of Tag F 309

Tag F 309 is based upon an alleged violation of 42 CF.R. § 483.25. That regulation requires:

> Each resident must receive and the facility must provide the necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being, in accordance with the comprehensive assessment and plan of care.

As reflected in Appendix PP of the State Operations Manual (SOM), the intent of 42 C.F.R. § 483.25 is to ensure that "the resident obtains optimal improvement or does not deteriorate within the limits of a resident's right to refuse treatment, and within the limits of recognized pathology and the normal aging process."[42] "Highest practicable physical, mental, and psychosocial well-being" is defined as "the highest possible level of functioning and well-being, limited by the individual's recognized pathology and normal aging process" and is "determined through the comprehensive resident assessment and by recognizing and competently and thoroughly addressing the physical, mental or psychosocial needs of the individual."[43] The SOM instructs the survey team to "[d]etermine if the facility is providing the necessary care and services based on the findings of the comprehensive assessment and plan of care" and, if services and care are being provided, "determine if the facility is evaluating the resident's outcome and changing the interventions if needed."[44]

With respect to recognition and management of pain, the SOM states:

> In order to help a resident attain or maintain his or her highest practicable level of well-being and to prevent or manage pain, the facility, to the extent possible:
>
> - Recognizes when the resident is experiencing pain and identifies circumstances when pain can be anticipated;
>
> - Evaluates the existing pain and the cause(s); and

[42] Ex. 6-1.
[43] *Id*.
[44] Ex. 6-2.

- Manages or prevents pain, consistent with the comprehensive assessment and plan of care, current clinical standards of practice, and the resident's goals and preferences.[45]

The SOM further stresses:

> Nursing home residents are at high risk for having pain that may affect function, impair mobility, impair mood, or disturb sleep, and diminish quality of life. The onset of acute pain may indicate a new injury or a potentially life-threatening condition or illness. It is important, therefore, that a resident's reports of pain, or nonverbal signs suggesting pain, be evaluated.
>
> The resident's needs and goals as well as the etiology, type, and severity of pain are relevant to developing a plan for pain management. It should be noted that while analgesics can reduce pain and enhance the quality of life, they do not necessarily address the underlying cause of pain. It is important to consider treating the underlying cause, where possible. Addressing underlying causes may permit pain management with fewer analgesics, lower doses, or medications with a lower risk of serious adverse consequences.[46]

Finally, the SOM states that possible indicators of pain include loss of function or inability to perform ADLs and difficulty sleeping.[47]

The Department contends that the Facility's management of Resident 48's pain was appropriately cited as a violation of Tag F 309. Although the initial therapy assessment of the Resident did mention his shoulder pain and the therapy itself addressed his shoulders as well as his knee, the Department argues that there is no indication that the Resident's shoulder pain was addressed apart from his physical and occupational therapy. The Department emphasized that pain is experienced in a subjective fashion. According to the core principles governing pain assessment and treatment, "the individual's self-report of pain is the single most reliable indicator of pain," and clinicians are expected to "accept and respect this self-report."[48] The Department contends that the Resident continued to have unmanaged pain that was on-going and significant, based primarily upon his frequent reports of pain in the 8 to 10 range and his statements to the surveyor that he was experiencing more pain when performing his ADLs. The Department acknowledged that the Facility did monitor the Resident's pain "somewhat," but found no evidence that Facility nurses reassessed that

[45] Ex. 6-12.
[46] Ex. 6-14.
[47] Ex. 6-17.
[48] Ex. 10 (Core Principles of Pain Assessment for Providers); *see also* Ex. 11 (Core Principles of Pain Treatment).

pain, evaluated the underlying causes, or changed the interventions to the extent necessary.[49]

The Facility argues that relevant records show that it did, in fact, adequately assess Resident 48 at the time of his admission and reassess him frequently throughout his stay. It points out that Facility staff provided the Resident with occupational and physical therapy, assisted in scheduling multiple doctor appointments for the Resident, and made updates and changes in his Plan of Care. The timing of the Resident's therapy was adjusted to match more closely with the time he was administered pain medication. The Facility also offered both pharmaceutical and non-pharmaceutical interventions to address the Resident's pain, such as cold packs, warm packs, repositioning, environment control, and distraction. Facility therapists also recommended other strategies to decrease the Resident's shoulder pain, such as asking staff to push him to activities in his wheelchair rather than wheeling himself or using his walker. The Facility emphasizes that the Resident had no cognitive deficits, was capable of communicating his needs, and was able to direct his own cares and inform the Facility nurses when he wanted pain medication. The Facility also maintains that the Resident made progress during his stay at the Facility. His ability to participate in ADLs increased over his six-week stay at the Facility, even though he may have experienced some discomfort. For example, the Resident initially required an assist of two to transfer to a bedside commode but later merely had a stand-by assistant. In addition, he was set up to be independent with respect to personal hygiene prior to January 10, 2013.[50]

After careful review of the record and the arguments of the parties, the Administrative Law Judge concludes that the Tag F 309 deficiency is supported in substance by the facts and should be affirmed. While it is evident that Facility staff did monitor Resident 48's pain during his six-week stay by noting his pain levels before and after physical therapy, occupational therapy, and the administration of medications and other interventions, its efforts fell short of meeting the requirements of 42 C.F.R. § 483.25 and the SOM. In particular, there is no evidence that the Facility took action to evaluate the causes of the significant levels of pain experienced by the Resident beginning on approximately December 20, 2012. On that date, the Physical Therapy Assistant noted that the Resident's pain was limiting his therapy and that the Resident had complained that his pain was not controlled by his medications. According to the PTA's notes, she told the Resident to discuss this with his doctor and also notified the Facility's nursing staff. However, there is no mention of this information in the Nursing Progress Notes, and no evidence that the situation prompted the nurses to conduct a pain assessment. In fact, according to the records supplied during the IIDR, no pain assessment occurred between December 17 and January 2, despite the consistently high pre-medication pain ratings given by the Resident. Nursing staff did not undertake a pain assessment until January 2, following the Resident's direct disclosure of his shoulder pain to his nurses on January 1.

[49] Comments of Christine Campbell; Comments of Sandra Nelson.

[50] Comments of D. Wozniak; Comments of Mindy Kapaun; Exs. B, C, E, I, W, Z, AP. The non-pharmacological interventions were sometimes refused by the Resident.

Under the circumstances, the Administrative Law Judge finds that the Tag F 309 deficiency is supported in substance. However, certain Findings included in the Form 2567 Statement of Deficiencies were not supported by any documents or commentary provided during the IIDR and should be deleted. Specifically, the following changes should be made to the Form 2567 (Exhibit 5):

(1) The last paragraph on page 5-9 (relating to allegations that boxes on a Medication Administration Record were not initialed for pain assessments due on December 29 and 31) should be deleted because the record lacked any support for that finding;

(2) The last paragraph on page 5-11 continuing to the top of page 5-12 (relating to the contents of a progress note dated January 3, 2013) should be deleted because the record lacked any support for that finding; and

(3) The second full paragraph of Exhibit 5 at 5-13 (relating to the contents of an OT Therapist Progress and Discharge Summary dated January 10, 2013) should be deleted from the Form 2567 because the record lacked any support for that finding.

The remaining findings are sufficient to support the substance of the deficient practice.

Scope and Severity of Tag F 309

As noted above, the Department alleged in the Statement of Deficiencies that the Facility's failure to conduct a reassessment when pain was identified and provide adequate pain management resulted in harm for Resident 48. The Administrative Law Judge cannot agree that the delay in the pain assessment between December 20 and January 2 caused actual harm to the Resident, or that the Facility failed to provide the Resident with adequate pain management. The Facility staff acted appropriately throughout the Resident's stay to mitigate his pain through the use of pain medication and other techniques. After the Resident told the Facility nurses on January 1, 2013, that he was experiencing shoulder pain, they called his primary care doctor the next day to schedule an appointment for him and also commenced a pain assessment. Facility staff also confirmed and arranged transportation for the Resident's appointment with his orthopedic doctor on January 17. The pain medication that had been prescribed to the Resident could be adjusted as needed and would have addressed not only the Resident's knee pain but also his shoulder pain. It is significant that the Resident's primary care doctor made no change in his pain medications as a result of the January 3 appointment, and his orthopedic doctor reduced his pain medications slightly as a result of his January 17 appointment. The orthopedic doctor also recommended intra-articular cortisone injections be given at the hospital, but there is no evidence if that occurred or what, if any, relief it provided. In addition, the orthopedic physician assured the Manager of the Facility's Rehabilitation Department that the Resident's pain and medical status was "'typical behavior' which he demonstrated with his previous knee [replacement]" and he believed the Facility's rehabilitation efforts and pain management

approaches were "great."[51] Finally, while expressing some belief that Ms. Murphy thought he was "faking" his pain, the Resident characterized his therapy and other treatment at the Facility as "good," said he was "doing great" post-discharge, and chose to return to the Facility a few months later.[52]

The Plain Flow Sheets maintained by the Facility showed a gradual reduction in the pre-medication pain reported by the Resident over the course of his stay (from levels of 8-10/10 during the first week of his stay to levels of 6-8/10 during his final week).[53] This improvement in pain management is supported by comparing the pain level the Resident reported at the time of his initial OT evaluation (9/10) with the pain level the Resident reported on January 8, 2013 (6-8/10).[54] The Resident also reported on December 14, December 21, December 28, January 1, and January 8 that E-Stim and/or IFC sensory treatment was helping to reduce the level of pain in his shoulders.[55] Moreover, between January 1, 2013, and his discharge on January 22, 2013, the Resident was asked during each shift if his pain program was effective for him. He always responded in the affirmative.[56] Because the Resident was lucid and able to effectively communicate his needs, there is no proper basis to doubt the accuracy of his responses.

Accordingly, the Administrative Law Judge recommends that the scope and severity level should be reduced to level D (no actual harm with the potential for more than minimal harm that is not immediate jeopardy).

Applicability of Tag F 329

Tag F 329 is based on an alleged violation of 42 C.F.R. § 483.25(l). That rule requires:

> Each resident's drug regimen must be free from unnecessary drugs. An unnecessary drug is any drug when used:
>
> (i) In excessive dose (including duplicate therapy); or
>
> (ii) For excessive duration; or
>
> (iii) Without adequate monitoring; or
>
> (iv) Without adequate indications for its use; or

[51] Ex. AM-1; Comments of A. Lymangood.
[52] Ex. AM; Comments of D. Wozniak.
[53] Comments of D. Wozniak; Exs. F, T, AG, AH, AI, and AJ.
[54] *Compare* Exhibits AA and D.
[55] Exs. A, D, AB, AC, and AD. In light of Mindy Kapaun's comments stressing that it was her practice to enter accurate notations in the Resident's record during or immediately after his therapy visits, it is unlikely that she "twisted" the Resident's words as the Resident alleged.
[56] Ex. R.

(v) In the presence of adverse consequences which indicate the dose should be reduced or discontinued; or

(vi) Any combinations of the reasons above.[57]

The SOM states that the intent of this provision is that "each resident's entire drug/medication regimen be managed and monitored" to ensure, among other things, that the regimen "helps promote or maintain the resident's highest practicable mental, physical, and psychosocial well-being" and that the resident "receives only those medications, in doses and for the duration clinically indicated to treat the resident's assessed condition(s)."[58] The SOM further indicates that "excessive dose" means "the total amount of any medication . . . given at one time or over a period of time that is greater than the amount recommended by the manufacturer's label, package insert, current standards of practice for a resident's age and condition, or clinical studies" and that "lacks evidence of . . . [a] review for the continued necessity of the dose; [a]ttempts at, or consideration of the possibility of, tapering a medication; and [a] documented clinical rationale for the benefit of, or necessity for, the dose . . . ."[59] The SOM defines "indications for use" as "the identified, documented clinical rationale for administering a medication that is based upon an assessment of the resident's condition and therapeutic goals and is consistent with manufacturer's recommendations and/or clinical practice guidelines . . . ."[60] "Insomnia" is defined in the SOM as "the inability to sleep characterized by difficulty falling asleep, difficulty staying asleep, early waking, or non-restorative sleep, which may result in impaired physical, social, or cognitive function."[61]

According to the SOM, the circumstances that warrant evaluation of the resident and medications may include situations in which "[a]n irregularity [is] identified in the pharmacist's monthly medication regimen review" or situations in which residents are "admitted on medications for an undocumented chronic condition or without a clear indication as to why a medication was begun or should be continued." In the latter situation, "[i]t is expected that the attending physician, pharmacist, and staff subsequently determine if continuing the medication is justified by evaluating the resident's clinical condition, risks, existing medication regimen, and related factors."[62]

The SOM contains a specific discussion of tapering considerations applicable to sedatives/hypnotics. If a resident remains on a sedative/hypnotic that is used "routinely and beyond the manufacturer's recommendations for duration of use," the SOM states that the facility should "attempt to taper the medication quarterly unless clinically contraindicated." The phrase "clinically contraindicated" is defined to encompass situations in which the "continued use of the medication is in accordance with relevant current standards of practice and the physician has documented the clinical rationale for why any attempted dose reduction would be likely to impair the resident's function or

[57] *See* Exs. 7-1 – 7-2.
[58] E. 7-2.
[59] Ex. 7-4.
[60] Ex. 7-5.
[61] *Id*.
[62] Ex. 7-13.

cause psychiatric instability . . ."; or the "resident's target symptoms returned or worsened after the most recent attempt at tapering the dose . . . and the physician has documented the clinical rationale for why any additional attempted dose reduction at that time would be likely to impair the resident's function or cause psychiatric instability . . . ."[63]

The "Highlights of Prescribing Information" relating to Ambien that are available through the FDA state that Ambien is a federally-controlled substance "because it can be abused or lead to dependence."[64] It is "indicated for the short-term treatment of insomnia characterized by difficulties with sleep initiation," and the clinical trials that were performed in support of its efficacy were 4-5 weeks in duration.[65] The recommended dose for adults is 10 mg once daily immediately before bedtime and the recommended dose for "elderly/debilitated patients/hepatically impaired" individuals is 5 mg once daily immediately before bedtime.[66] Those who are age 60 or older are considered to be geriatric.[67] The FDA information also indicates that "[d]osage adjustment may be necessary when Ambien is combined with other CNS [central nervous system] depressant drugs because of the potentially additive effects."[68]

In this case, the Department maintained that the Facility failed in its responsibility to monitor and identify unnecessary medications with respect to the Resident's use of Ambien and did not address the issue in its assessments or interventions or discuss it with the Resident's physician. It contended that Resident 48 received a high dose of Ambien for an extended period of time during his stay at the Facility (based on his physician's PRN prescription), with no plan for discontinuance. The Department emphasized that the Resident's dose of 10 mg exceeded the recommended dosage for adults over 60, and pointed out that the dosage perhaps should have been further adjusted because the Resident was also taking both short- and long-acting narcotics. The Department argued that the Facility was aware that there may have been reasons other than actual insomnia for the Resident's request for Ambien, such as pain, depression, and anxiety.[69]

The consultant pharmacist interviewed by the Department survey team indicated that Ambien would help a person sleep but should not be used as an analgesic and, if pain was causing Resident 48 to be awake, it would be "best to concentrate on pain versus using a sedative hypnotic for sleep." The pharmacist also stated that "Ambien is not considered an adjunct therapy" with pain medication.[70] When the Department survey team interviewed the Facility's Interim Director of Nursing, she agreed that Ambien "would not be indicated if the cause of sleeplessness was pain."[71]

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[63] Ex. 7 at 7-24.
[64] Ex. 12 at 12-20.
[65] *Id*. at 12-2.
[66] *Id*.
[67] Ex. 12 at 12-12.
[68] Ex. 12 at 12-2, 12-4.
[69] Comments of C. Campbell; Comments of S. Nelson.
[70] Ex. 5 at 5-19 – 5-20.
[71] Ex. 5 at 5-19.

In response, the Facility argued that it did, in fact, fully comply with this rule provision. The Facility's Regional Director of Clinical Operations indicated that it is the Facility's standard practice to go through the risks and benefits of medications within 24 hours of a resident's admission. In addition, a pharmacist comes into the Facility and reviews the medications received by all residents on a monthly basis. The Facility contended that both of these approaches help identify and address any unnecessary medications. When the pharmacist reviewed the Resident's records shortly after his admission, she advised the Facility to complete a sleep assessment for the Resident. The Facility thereafter completed the sleep assessment, which demonstrated that Ambien was effective for the Resident. The Department's survey occurred prior to the next date that the pharmacist would have visited to review the Resident's records.[72]

The Facility maintained that Ambien was given to the Resident only when he reported difficulty sleeping, and not for pain. If the Resident reported pain, the nurses would give him pain medication. The Facility emphasized that Ambien was a PRN medication that the Resident took prior to his admission to the Facility and continued to take when he informed nursing staff at the Facility that he was having difficulty sleeping. Facility staff learned after the survey was completed that the Resident had initially been prescribed Ambien in 2010, and had been getting the prescription refilled regularly every 30 days since that time.[73]

During pain assessment interviews that were conducted on December 17, 2012, and January 22, 2013, the Resident said that pain had not interfered with his sleep during the prior five days.[74] However, during his admission pain assessment on December 11, 2012, and during a later assessment on January 2, 2013, the Resident said that pain had interfered with his sleep during the prior five-day period.[75]

After consideration of the documents and the arguments of the parties, the Administrative Law Judge concludes that the Tag F 309 deficiency is supported in substance by the facts and should be affirmed. As the Facility's reviewing pharmacist apparently noted shortly after the Resident's admission, the amount of Ambien that had been prescribed for the Resident exceeded the recommended dosage for adults over 60 and also may have been high in light of the Resident's other prescriptions for short- and long-acting narcotics that were CNS depressants. The record shows that the Facility failed to discuss with the Resident's physician and/or the Facility's medical director the dosage of Ambien that had been prescribed for the Resident or address that issue in its assessments or interventions to determine whether the medication was unnecessary. The Facility also should have considered whether the excessive duration of the Resident's Ambien prescription was appropriate and whether a plan to taper off the medication should have been put in place.

There is no evidence, however, that Ambien was improperly given to the Resident in an effort to reduce his pain, depression, or anxiety; to the contrary, the

[72] *Id*.; Ex. 8 at 8-7.
[73] Comments of D. Wozniak.
[74] Exs. N and AK; Comments of D. Wozniak.
[75] Exs. V and AF; Comments of D. Wozniak.

Facility's records demonstrate that it was given to the Resident when he asked for it because he was having trouble falling asleep. In fact, in some instances, the Resident was given Ambien and, when he complained of pain later in the night, he was given pain medication at that point.[76] Facility records show that Ambien was given to the Resident for insomnia on at least seven occasions during December 2012 and three occasions during January 2013. In each instance, the nurses documented that it was being given for insomnia.[77] The Resident's Ambien usage thus decreased over the course of his stay with the Facility, which the Facility's Regional Director of Clinical Operations indicated commonly occurs as residents become accustomed to their new environment.[78]

While the deficiency is supported in substance, certain Findings included in the Form 2567 Statement of Deficiencies were not supported by any documents or commentary provided during the IIDR and should be deleted. Specifically, the following changes should be made to the Form 2567 (Exhibit 5):

(1) The last three sentences of the first full paragraph on page 5-17 (relating to the contents of the Minimum Data Set dated December 20, 2012, and the Mood State Care Area Assessment dated December 20, 2012) should be deleted because the record lacked any support for those findings;

(2) The third paragraph on page 5-17 (relating to the contents of the After Discharge Orders dated December 6, 2012) should be deleted because the record lacked any support for that finding. This language should be replaced with the following information drawn from Exhibit 9, page 9-1:

> The Internal Medicine Hospitalist Note dated December 10, 2012, noted that R48 "[n]eeded BiPAP post-op for respiratory insufficiency" and stated that R48 should "[c]onsider outpatient OSA [Obstructive Sleep Apnea] testing."

(3) The second full paragraph on page 5-18 (relating to the contents of the Mood and Behavior Symptom Assessment/Plan of Care dated December 12, 2012) should be deleted because the record lacked any support for that finding;

(4) The third full paragraph on page 5-18 (relating to the Social Services Short Stay Plan of Care dated December 12, 2012) should be deleted because the record lacked any support for that finding;

[76] Exs. I and AO.
[77] Exs. I, O, Q, AO, and 8 at 8-12.
[78] Comments of D. Wozniak.

(5) The last paragraph on page 5-18 which continues on the top of page 5-19 (relating to a psychology Diagnostic Assessment Report dated December 24, 2012) should be deleted because the record lacked any support for that finding; and

(6) The portion of the second full paragraph on page 5-19 that relates to Medication Administration Records for December 2012 should be deleted because the record lacked any support for that finding. This language should be replaced with the following information drawn from Exhibits I, O, Q, AO, and 8 at 8-12:

> Facility records revealed that R48 received Ambien on seven occasions in December, 2012, and three occasions (1/1/13, 1/4/13, and 1/5/13) in January, 2013. The medical record lacked evidence of any other interventions used for insomnia.

The remaining findings are sufficient to support the substance of the deficient practice.

Scope and Severity of Tag F 329

This deficiency was cited at a scope and severity level of D. Level D reflects a determination that this deficiency was isolated in scope and resulted in minimal discomfort to the resident and/or had the potential (not yet realized) to compromise the resident's ability to reach his highest practicable physical, mental or psychosocial well-being. In the current case, the high dose and lengthy duration of the Resident's Ambien use had the potential to adversely affect the ability of Resident 48 to reach his highest practicable well-being.

Accordingly, the Administrative Law Judge concludes that the Department has shown that this deficiency was appropriately cited at a D level.

B. L. N.